



By US & Electronic Mail

July 19, 2024

Owen Foster, Chair
Green Mountain Care Board
144 State Street
Montpelier, Vermont 05602
owen.foster@vermont.gov

**Re: The University of Vermont Medical Center Inc.
Request for Relief from Sanctions –
Central Sterile Reprocessing Equipment Replacement**

Dear Chair Foster:

By way of this letter, The University of Vermont Medical Center Inc. (“UVM Medical Center”) requests prospective relief from sanctions for future, limited capital expenditures essential for the functionality of its Central Sterile Reprocessing (“CSR”) Department, *prior to* the issuance of a Certificate of Need (“CON”) for a later, related project. UVM Medical Center intends to file, in the spring of 2025, an application for a CON to permit the full redesign and renovation of its CSR space located within the hospital (the “CSR Renovation Application”). Nevertheless, due to the end-of-life condition of several CSR autoclaves, low-temp sterilizers, instrument washers, and pack and prep tables, UVM Medical Center finds it necessary to immediately purchase and install certain replacement equipment, at an approximate cost of \$3,539,316,¹ while it prepares the CSR Renovation Application. UVM Medical Center will (and must) replace this equipment even if it decides not to move forward with the larger project.

The proposed expenditures are below the CON jurisdictional threshold and would not, standing alone, require either a CON or prospective relief from sanctions. UVM Medical Center, however, acknowledges that the expenditures for replacement CSR equipment could be viewed by the Green Mountain Care Board (the “Board”) as “related project components” of the future CSR Renovation, pursuant to Board Rule 4.207. It is not the intention of UVM Medical Center to avoid the Board’s jurisdiction; rather, it is the intention of the hospital, through this letter, to keep the Board apprised of the expenditures that must be made in advance of the CSR Renovation Application and approval to preserve access to surgical services for Vermonters and to avoid sanctions in doing so.

¹ Inclusive of a 20% contingency.

Rationale

The CSR Department at UVM Medical Center—which is responsible for the decontamination, sterilization, preparation and packing, and storage of instruments used in surgical procedures—is critical to the operation of the hospital and maintaining access to surgery. Several of the existing autoclaves, low-temp sterilizers, instrument washers, and pack and prep tables are end-of-life or no longer suitable for purpose and have been identified as needing replacement by CSR staff (with some support from ECRI and Steris), and many of those pieces of equipment are experiencing down-time related to age and condition.

The table below lists the CSR equipment UVM Medical seeks to replace. Much of this equipment is operating well beyond the manufacturer’s recommended number of use cycles, as noted in detail in Exhibit A.

Estimated costs for Emergent/Urgent CSR Needs:

Emergent/Urgent Need	Per Unit Cost	Total Cost
Replacement of existing Steam Autoclaves Qty 5	\$166,500	\$832,500
Replacement of existing Low-temp Sterilizers Qty 2	\$157,500	\$315,000
Replacement of existing Instrument Washers Qty 4	\$133,500	\$534,000
Replacement of existing Pack and Prep tables Qty 14	\$11,995	\$167,930
-Mechanical/electrical support work for replacing steam autoclave sterilizers, filters, and instrument washers - Electrical/data connections and floor patch for replacing 14 Pack and Ship tables - Phase 2 critical water improvements for ST108 compliance including clean steam generation. - Replace ceiling, lights, registers, diffusers, and grills and apply one coat of epoxy	N/A	\$1,100,000
Project Contingency 20%	N/A	\$589,886
Total Expenditure	N/A	\$3,539,316

Analysis

Full relief from sanctions for making the capital expenditures necessary to replace the CSR equipment is merited under Board Rule 4.700, which requires the Board to consider the following mitigating factors in determining appropriate sanctions for violations of the CON laws:

- (a) whether the entity filed a good faith letter of intent or letter of inquiry;
- (b) whether the entity reasonably relied on a no jurisdiction determination from the Board;

- (c) whether the project will cause an increase in costs to the health care system;
- (d) whether the project is likely to reduce or contain the cost of health care services;
- (e) whether the project is otherwise consistent with Certificate of Need criteria;
- (f) in the case of a facility that incorrectly projects it would not exceed monetary jurisdictional thresholds, whether the erroneous projection was reasonable based on a totality of the underlying facts and circumstances;
- (g) any other mitigating or aggravating factors."²

The expedited replacement of the end-of-life CSR equipment is crucial to avoid increasing down-time for repairs and the unintended consequence of limiting surgical services due to the unavailability of clean, sterile instrumentation. The equipment replacement will not cause an increase in costs to the Vermont health care system and falls below the \$3,690,000 monetary jurisdictional threshold for capital expenditures by hospitals.³ The equipment expenditures also align with CON criteria (e.g., the cost is reasonable, there is a clear need, the replacement equipment will have the effect of preserving access, and the replacements will not impact other services).

Simply put, the equipment replacement and installation prior to the approval of the CSR Renovation CON is driven by timing. While this work was originally slated to be part of one large project, UVM Medical Center estimates that the replacement equipment could be ordered and installed *in as few as six months*. The entire CSR Renovation, on the other hand, will not be complete until late spring of 2026, assuming the planning, application, deliberation, approval, and construction moves forward without issue or delay. The ability to make limited expenditures now to replace the end-of-life equipment will keep the CSR Department running in the meantime.

Conclusion

We appreciate the GMCB's consideration of this Request for Relief from Sanctions as the UVM Medical Center seeks to support its CSR Department and preserve access to surgical services to Vermonters.

Sincerely,



Amanda S. Angell
Associate General Counsel
The University of Vermont Health Network

Enclosure

² Board Rule 4.700.

³ See [GMCB Certificate of Need Bulletin](#) (Apr. 12, 2023) (revising Certificate of Need Monetary Jurisdictional Thresholds for hospitals and non-hospitals).

cc: Michael Barber
Donna Jerry
Stephen Leffler, MD

Exhibit A – Existing Equipment Condition as of September 2023

Item Description	Equipment Location	Install Date	Age	Useful Life AHA	Remaining UL in Years	Cycle Count	National Avg Annual Cycle Count	National Avg UL in Cycles	Remaining UL in Cycles	Product Group	Justification
						RED values indicate actual count may be higher than reported					
V-PRO MAX, SD, CAB, 208/230V, 60HZ ENGLISH (OOME)	CSR VPRO # 23	03/29/2017	7	7	0	9285	750	5250	-4035	Low Temp Sterilizers	Over useful life based on cycle count. Higher than average service activity
V-PRO MAX, SD, CAB, 208/230V, 60HZ ENGLISH	CSR V-PRO #18	01/23/2015	9	7	-2	13113	750	5250	-7863	Low Temp Sterilizers	Over useful life based on both cycle count and years.
AMSCO 400 20X20X38 PVAC SD SLIDE REC STM	CSR Sterilizer #1	10/29/2012	12	15	3	11124	750	11250	126	Steam Sterilizers	At useful life based on cycle count. Replacement with larger capacity sterilizer to accommodate increased procedural volume
60 IN. PLATFORM PREVAC STERILIZER,DBL HINGLE,STM,REC 2/W,LR, 208/240V	CSR Sterilizer #8	08/03/2005	19	15	-4	36483	1050	15750	-20733	Steam Sterilizers	Over useful life based on cycle count and years.
60 IN. PLATFORM PREVAC STERILIZER,DBL HINGLE,STM,REC 2/W,LR, 208/240V	CSR Sterilizer #10	08/03/2005	19	15	-4	51219	1050	15750	-35469	Steam Sterilizers	Over useful life based on cycle count and years.
60 IN. PLATFORM PREVAC STERILIZER,DBL HINGLE,STM,REC 2/W,LR, 208/240V	CSR Sterilizer #9	08/03/2005	19	15	-4	24030	1050	15750	-8280	Steam Sterilizers	Over useful life based on cycle count and years. Higher than average call volume
60 IN. PLATFORM PREVAC STERILIZER,DBL HINGLE,STM,REC 2/W,LR, 208/240V	CSR Sterilizer # 7	08/03/2005	19	15	-4	13238	1050	15750	2512	Steam Sterilizers	Over useful life based on cycle count and years. Higher than average call volume
60 IN. PLATFORM PREVAC STERILIZER,DBL HINGLE,STM,REC 2/W,LR, 208/240V	CSR Sterilizer #6	08/03/2005	19	15	-4	39054	1050	15750	-23304	Steam Sterilizers	Over useful life based on cycle count and years.
RELIANCE VISION SC 460-480V 3Ph 60Hz STEAM HTD	CSR Washer #2	02/20/2017	7	10	3	19531	1550	15500	-4031	Washers	Over useful life based on cycle count. Higher than average service activity.
RELIANCE VISION SC 460-480V 3Ph 60Hz STEAM HTD	CSR Washer #4	02/15/2017	7	10	3	23825	1550	15500	-8325	Washers	Over useful life based on cycle count. Higher than average service activity.
RELIANCE VISION SC 460-480V 3Ph 60Hz STEAM HTD	CSR Washer #3	02/20/2017	7	10	3	21814	1550	15500	-6314	Washers	Over useful life based on cycle count
RELIANCE VISION SC 460-480V 3Ph 60Hz STEAM HTD	CS WASHER # 1	02/17/2017	7	10	3	32165	1550	15500	-16665	Washers	Over useful life based on cycle count